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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,449	12/12/2003	Shawn David Roman	5490-259COB	2026
27572 7590 08/24/2007 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 08/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/735,449	Applicant(s) ROMAN ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7,9,16,17 and 21-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10-15,18-20 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The examiner acknowledges that applicant intends to file a Terminal Disclaimer at a later date. Until such is filed, the Double Patenting Rejection stands.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8, 10-15 and 18-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,685,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the two sets of claims lies in the fact that the patent claims includes many more elements and is thus more specific than the application claims. It has been held that the generic invention is anticipated by the species. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 112

The amendment to claim 11 filed on June 14th, 2007 is acknowledged and accepted by the examiner. The previous rejection under 35 U.S.C. 112, 2nd paragraph is hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 8 recites, "wherein the post includes external ribs." In the specification, elements 128 were defined as ribs/threads. Therefore, since applicant has already claimed threads in claim 1, applicant cannot also comprise ribs therefore creating a new matter limitation.

Claim 31 recites, "wherein the threads are defined along an outermost dimension of the post." Clearly from the Figures, the outermost dimension of the post is at 121/122', which is not threaded 128.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "claim 12 ... **the key**" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, 12-15 and 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hopf (US Patent 5,814,046).

Hopf discloses a device (**Figures 3 and 5**) comprising: a cap (**23**) having a first engaging member (internal threading); a base (**3**); a post (**1**) with threading/ribbing (**11**) extending substantially an entire length of the post; the post (**1**) is rotatably attached to the base and cap; the post (**1**) having a D-shaped keyed section (**12**) with a torque-limiting section (where **12** turns to **11**) inherently preventing a level of over tightening of the cap relative to the base; and an applier (**14, Figure 5**) having a keyed bore (**28**) to interact with the keyed section (**12**) of post (**1**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8, 10-15, 18-20 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuras (US Patent 6,585,739) in view of Bremer et al (US Patent 6,022,351).

Kuras discloses a device (**Figures 1-9**) comprising: a cap (**50**) with teeth (**92**); a base (**44**); a post (**46 or 250**) having a threading/ribbing extending substantially an entire length of the post; the post having a keyed section (**142**) to receive an applier (**Column 4, Lines 40-42**); and the device made of titanium (**Column 3, Lines 15-18**).

Kuras discloses all of the claimed limitations except is silent of a torque-limiting feature. It is well-known in the art to use torque-limiting, force limiting, and/or frangible components to limit the force in tightening components, such as taught by Bremer et al (**Column 4, Lines 44-48**). Bremer et al explicitly state that the post element can have at least one weakened section of significantly less thickness to prevent over tightening thereby preventing ratchet teeth from breaking. As seen in Kuras, ratchet teeth and threaded engagement are both anticipated and interchangeable.

It would have been obvious to one having ordinary skill in the art at the time of invention to provide for torque/force limiting structure (usually a reduced cross-sectional area relative to the rest of the force transmission member) to the device of Kuras in

order to prevent over tightening of the device, which in turn would cause harm to the subject being operated on.

It would have further been a matter of design choice to one having ordinary skill in the art at the time of the invention to choose where such break points are located such as where the keyed section meets the rest of the shaft. Applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configuration a person of ordinary skill in the would find obvious in order to provide for a means to prevent over tightening. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuras in view of Bremer et al and optionally in further view of Hopf.

Kuras in view of Bremer at disclose and teach all of the claimed limitations except for a D-shaped cross-section for the torque-limiting feature where the rounded portion is substantially equivalent with an outer radius of the rest of the post.

As stated above, reducing the cross-sectional area of a shaft has been a well known matter of creating a torque-limiting section. It would have been a matter of preference should one desire to equally remove material from all around (like Bremer et al) or merely make a single cut inward from a given direction (thereby forming a D-shape cross-section at the weakened joint) with predictable results.

Also, Hopf shows a transmission member (12), which inherently controls the total amount of torque capable of being transmitted to a post. It would have been a mere substitution of workable parts to utilize the D-shaped transmission element of Hopf for

the hexagonal (142) transmission of Kuras to provide for a means to drive the post with predictable results.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopf.

Hopf discloses all of the claimed limitations except for the device made of non-resorbable titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device of titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed June 14th, 2007 have been fully considered but they are not persuasive.

In response to applicant's argument that "Hopf fails to teach securing a bone plate or cranium between a cap and base", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant further argues that feature (12) in Hopf is a not a torque limiting feature. The portion has a reduced cross-sectional area relative to the member it is intended to

act upon (which is of the same material), therefore it is a "torque-limiting feature" given the broadest reasonable interpretation.

Applicant's arguments in regard to the combination of Kuras in view of Bremer et al is also not found persuasive. The rejection previously was stating that Bremer et al merely showed what was already stated as known in the art, in that torque-limiting features are used to prevent over-tightening through the use of a reduced cross-sectional area. Beyond that, the rationale to combine a torque-limiting feature to the device of Kuras was for the general use of avoiding over tightening of the device (which prevents damage to the device as well as patient) as a matter of a predictable result and within the ability of one having ordinary skill in the art. See *KSR International Co. v. Teleflex Inc.*, 550 U.S., 82 USPQ2d 1385 (2007).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a):

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

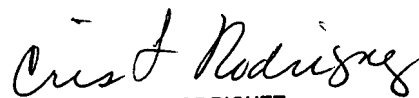
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
August 18th, 2007



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